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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Denis MARTIN et al.

Serial No.: 10/650,123

Group Art Unit: 1645

Filed: August 28, 2003

Examiner: Jennifer E. GRASER

For: PHARMACEUTICAL COMPOSITIONS

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

Timing and Fees

- ☐ Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:
- ☐ within three months of the filing date of a national application other than a CPA under § 1.53(d);
 - ☐ within three months of the actual filing date of the national phase of a PCT application; OR
 - ☐ before the mailing of a first substantive office action (including after filing of an RCE).
- ☒ Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:
- a final rejection under 37 C.F.R. 1.113;
 - termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
 - a notice of allowance under 37 C.F.R. § 1.311; and

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180.00 OP

is accompanied by:

- ☐ the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR
- ☒ a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).

☐ Under 37 C.F.R. § 1.97(d), this information disclosure statement is filed after the mailing date of the following actions which have not been withdrawn:

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- ☐ OR a notice of allowance under 37 C.F.R. § 1.311;

AND is filed on or before payment of the issue fee; AND is accompanied by:

the statement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of \$180.00 under 37 C.F.R. § 1.17(p).

Statements Under 37 C.F.R. 1.97(e)

- ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.

Cited Materials

- ☐ Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. _____, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).
- ☒ Copies of materials listed but not attached were cited in an international search report dated March 5, 2004.
- ☐ Not required by 37 CFR § 1.98.
- ☒ Copies of the materials listed are attached (except for the foregoing).

Non-English Language References

- ☒ An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).
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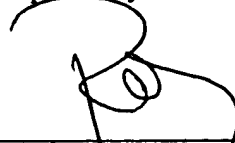
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Payment of Fees Due (If Any):

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☒ The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,



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Attorney Docket No.: IDB-0033

Date: January 13, 2006

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/650,123
				Filing Date	August 28, 2003
				First Named Inventor	Denis MARTIN et al.
				Group Art Unit	1645
				Examiner Name	Jennifer E. GRASER
				Attorney Docket Number	IDB-0033
Sheet	1	of	3		

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Examiner Signature		Date Considered	
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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached. Number refers to English language corresponding family member.

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Sheet	2	of	3

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	3	Martin et al.; "Highly Conserved <i>Neisseria meningitidis</i> Surface Protein Confers Protection against Experimental Infection," J. Exp. Med, 7 April 1997, pages 1173-1183, Vol. 185, no. 7.	
	4	Martin et al. "Candidate <i>Neisseria meningitidis</i> NspA vaccine," Journal of Biotechnology, 83 (2000) 27-31.	
	5	Carmenate et al.; Recombinant Opc protein from <i>Neisseria meningitidis</i> reconstituted into liposomes elicits opsonic antibodies following immunization; Biotechnol. Appl Biochem (2001) 34, 63-69	
	6	Christodoulides et al.; Immunization with recombinant class 1 outer-membrane protein from <i>Neisseria meningitidis</i> : influence of liposomes and adjuvants on antibody avidity, recognition of native protein and the induction of a bactericidal immune response against meningococci; Microbiology (1998) 144, 3027-3037; XP-002271046	
	7	Martin et al.; Recombinant NspA incorporated into liposomal vesicles induces functional antibodies; Vaccine Research Unit, Laval University Medical Center, Ste-Foy, Quebec, Canada <i>Norway Sept 02</i>	
	8	Sacchi et al.; Considerations on the use of <i>Neisseria meningitidis</i> class 5 proteins as meningococcal BC vaccine components; Vaccine, 1995, Volume 13, Number 1, pp. 112-118	
	9	Tinsley et al.; Antibodies recognizing a variety of different structural motifs on meningococcal Lip antigen fail to demonstrate bactericidal activity; Journal of General Microbiology (1992), 138, 2321-2328	
	10	Moe et al.; Functional Activity of Anti-Neisserial Surface Protein A Monoclonal Antibodies against Strains of <i>Neisseria meningitidis</i> Serogroup B; Infection and Immunity, June 2001, pp. 3762-3771	
	11	Hou et al.; Conformational Epitopes Recognized by Protective Anti-Neisserial Surface Protein A Antibodies; Infection and Immunity, Dec. 2003, pp. 6844-6849, vol. 71, no. 12.	
	12	Vandeputte-Rutten et al.; Crystal Structure of Neisserial Surface Protein A (NspA), a Conserved Outer Membrane Protein with Vaccine Potential; Journal of Biological Chemistry; Vol. 278, No. 27, Issue of July 4, pp 24825-24830, 2003	
	13	Moe et al.; Sequential Immunization with Vesicles Prepared from Heterologous <i>Neisseria meningitidis</i> Strains Elicits Broadly Protective Serum Antibodies to Group B Strains; Infection and Immunity, Nov. 2002, p 6021-6031, vol. 70, no. 11.	
	14	Korojev et al., Induction of Antimeningitis Immunity by Synthetic Peptides: III. ¹ Immunoactive Synthetic Fragments of the NspA Protein from <i>Neisseria meningitidis</i> ; Russian Journal of Bioorganic Chemistry, Vol. 28, No. 4, 2002, pp. 263-268	
	15	Arigita et al.; Restored functional immunogenicity of purified meningococcal PorA by incorporation into liposomes; Vaccine 21 (2003) 950-960	
	16	Wright et al.; Immunization with the Recombinant PorB Outer Membrane Protein Induces a Bactericidal Immune Response against <i>Neisseria meningitidis</i> ; Infection and Immunity, Aug. 2002, pp. 4028-4034, vol. 70, no. 8.	

17	Arigita et al.; Liposomal Meningococcal B Vaccination: Role of Dendritic Cell Targeting in the Development of a Protective Immune Response; Infection and Immunity, Sept. 2003, p. 5210-5218, vol. 71, no. 9.	
18	Jolley et al.; Immunization with Recombinant Opc Outer Membrane Protein from <i>Neisseria meningitidis</i> : Influence of Sequence Variation and Levels of Expression on the Bactericidal Immune Response against Meningococci; Infection and Immunity, June 2001, p. 3809-3916, vol. 69, no. 6.	
19	Idanpaan-Heikkilä et al.; The antibody response to a prototype liposome vaccine containing <i>Neisseria meningitidis</i> outer membrane protein P1 produced in <i>Bacillus subtilis</i> ; Vaccine, Vol. 13, No. 16, pp. 1501-1508, 1995.	
20	Parmar et al.; Biophysical and antigenic characterization of gonococcal protein I incorporated into liposomes; Vaccine, Vol. 15, no. 15, pp. 1641-1651, 1997	
21	Niebla et al.; Immunogenicity of recombinant class 1 protein from <i>Neisseria meningitidis</i> refolded into phospholipids vesicles and detergent; Vaccine 19 (2001) 3568-3574	
22	Ward et al.; Expression of <i>Neisseria meningitidis</i> class 1 porin as a fusion protein in <i>Escherichia coli</i> : the influence of liposomes and adjuvants on the production of a bactericidal immune response; Microbial Pathogenesis 1996; 21: 499-512	
23	Morley et al.; Vaccine prevention of meningococcal disease, coming soon?; Vaccine 20 (2002) 666-687	
24	Vermont et al.; Recent developments in vaccines to prevent meningococcal serogroup B infections; Current Opinion in Molecular Therapeutics, 2003, 5(1): 33-38	
25	Bethell et al.; Meningococcal vaccines; Expert Rev. vaccines, 1(1), 75-84 (2002)	
26	Rosenqvist et al.; The 5C Protein of <i>Neisseria meningitidis</i> Is Highly Immunogenic in Humans and Induces Bactericidal Antibodies; The Journal of Infectious Diseases 1993; 167:1065-73	

Examiner
Signature

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Considered

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THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Denis MARTIN et al.

Serial No.: 10/650,123

Group Art Unit: 1646

Filed: August 28, 2003

Examiner: Not Yet Assigned

For: PHARMACEUTICAL COMPOSITIONS

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T = document cited to understand the theory or principle underlying the invention

E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date

D = cited in the application

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☐ Translation of other relevant information on foreign search report

Other Information

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☒ The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,



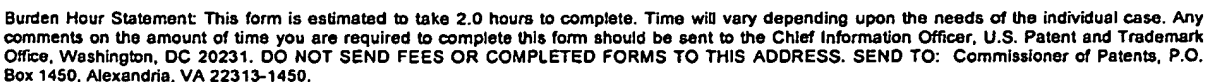
Richard M. Lebovitz, Reg. No. 37,067
Attorney for Applicants

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Facsimile: (703) 243-6410

Attorney Docket No.: PHARMA-0330

Date: June 14, 2004

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 3

Complete If Known

Application Number	10/650,123
Filing Date	August 28, 2003
First Named Inventor	Denis MARTIN et al.
Group Art Unit	1646
Examiner Name	Not Yet Assigned
Attorney Docket Number	PHARMA-0330

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
		Denis Martin et al., J. of Biotechnology (2000), Vol. 83 No. 1-2, pp. 27-31, "Candidate <i>Neisseria meningitidis</i> NspA vaccine"	
		Tania Carmenate et al., Biotechnology and Applied Biochemistry 2001, Vol. 34, No. 1, pp. 63-69, "Recombinant Opc protein from <i>Neisseria meningitidis</i> reconstituted into liposomes elicits opsonic antibodies following immunization"	
		Christodoulides et al., Microbiology (1998) 144, No. 11, pp. 3027-3037, "Immunization with recombinant class 1 outer-membrane protein from <i>Neisseria meningitidis</i> : Influence of liposomes and adjuvants on antibody avidity, recognition of native protein and the induction of a bactericidal immune response against meningococci"	
		D. Martin et al., Poster no 672 presented in Oslo, Norway in Sept. 2002. "Recombinant NspA incorporated into liposomal vesicles induces functional antibodies"	
		Claudio Tavares Sacchi et al., "Considerations on the use of <i>Neisseria meningitidis</i> class 5 protein as meningococcal BC vaccine components," Vaccine 1995 Vol. 13, pp. 112-118,	
		Colin R. Tinsley et al., J. of General Microbiology 1992 138, 2321-2328. "Antibodies recognizing a variety of different structural motifs on meningococcal Lip antigen fail to demonstrate bactericidal activity"	
		G.R. Moe et al., Infection and Immunity, June 2001, Vol. 69 No. 6, pp. 3762-3771, "Functional Activity of Anti-Neisserial Surface Protein A Monoclonal Antibodies against Strains of <i>Neisseria meningitidis</i> Serogroup B"	
		Victor C. Hou et al., Infection and Immunity, Dec. 2003, Vol. 71, No. 12, pp. 6844-6849, "Conformational Epitopes Recognized by Protective Anti-Neisserial Surface Protein A Antibodies"	
		Lucy Vandeputte-Rutten et al., The Journal of Biological Chemistry, July 4, 2003, Vol. 278, No. 27, pp. 24825-24830, "Crystal Structure of Neisserial Surface Protein A (NspA), a Conserved Outer Membrane Protein with Vaccine Potential"	
		Gregory R. Moe et al., Infection and Immunity Nov. 2002, Vol. 70, No 11. pp. 6021-6031, "Sequential Immunization with Vesicles Prepared from Heterologous <i>Neisseria meningitidis</i> Strains Elicits Broadly, etc."	
		D. O. Korojev et al., Russian J. of Bioorganic Chemistry, Vol. 28, No. 4, 2002, pp. 263-268. "Induction of Antimeningitis by synthetic Peptides: III. Immunoactive Synthetic Fragments of the NspA Protein from <i>Neisseria meningitidis</i> "	
		Carmen Arigita et al., Vaccine 21 (2003) pp. 950-960, "Restored functional immunogenicity of purified meningococcal PorA by incorporation into liposomes"	
		J. Claire Wright et al., Infection and Immunity, August 2002, p. 4028-4034 Vol. 70, No. 8, "Immunization with Recombinant PorB Outer Membrane Protein Induces a Bactericidal Immune Response against <i>Neisseria meningitidis</i> "	
		Carmen Arigita et al., Infection and Immunity, Sept 2003, p. 5210-5218, Vol. 71, No. 9, "Liposomal Meningococcal B Vaccination: Role of Dendritic Cell Targeting in the Development of a Protective Immune Response"	

2	Keith A. Jolley et al., Infection and Immunity, June 2001, p. 3809-3916, Vol. 69, No. 6, "Immunization with Recombinant Opc Outer Membrane Protein from <i>Neisseria meningitidis</i> : Influence of Sequence Variation and Levels of Expression on the Bactericidal Immune Response against Meningococci"	
	Idanpaan-Heikkila et al., Vaccine 1995, Vol. 13, No. 16, pp. 1501-1508, "The antibody response to a prototype liposome vaccine containing <i>Neisseria meningitidis</i> outer membrane protein P1 produced in <i>Bacillus subtilis</i> "	
	Manjeet M. Parmar et al., Vaccine 1997, Vol. 15, No. 15, pp. 1641-1651, "Biophysical and antigenic characterization of gonococcal protein I incorporated into liposomes"	
	Immunogenicity of recombinant class I protein from <i>Neisseria meningitidis</i> refolded into phospholipids vesicles and detergent, Olivia Niebla et al., Vaccine 19 (2001) 3568-3574	
	Stephen J. Ward et al., Microbial Pathogenesis 1996; Vol. 21, pp. 499-512. "Expression of <i>Neisseria meningitidis</i> class 1 porin as a fusion protein in <i>Escherichia coli</i> : the influence of liposomes and adjuvants on the production of a bactericidal immune response"	
	Sara L. Morley et al., Vaccine (2002) Vol. 20, 666-687, "Vaccine prevention of meningococcal disease, coming soon?"	
	Clementien L. Vermont et al., Current Opinion in Molecular Therapeutics 2003, Vol. 1, pp 33-38, "Recent developments in vaccines to prevent meningococcal serogroup B infections"	
	Bethell & Pollard, "Meningococcal Vaccines", , Expert Rev. Vaccines 1(1) (2002), pp. 75-84	
	Einar Rosenqvist et al., "The 5C Protein of <i>Neisseria meningitidis</i> Is Highly Immunogenic in Humans and Induces Bactericidal Antibodies", J. Infectious Diseases (1993), 167: pp. 1065-1073	

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